**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 8-708/S-023

Wellspring Pharmaceutical Corporation
Attention: Mr. Drew Karlan
1430 Highway 34
Neptune, NJ 07753-6807

Dear Mr. Karlan:

Please refer to your supplemental new drug application dated August 29, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Dibenzyline (phenoxybenzamine HCl) 10 mg Capsules.

We acknowledge receipt of your submissions dated September 4 and November 14 and 18, 2003.

This supplemental new drug application provides for draft labeling revised to remove the following statements from the container label:

> **Warning**: Potent drug- Not to be used except under close supervision of a physician.
>
> **Important**: Use safety closures when dispensing this product unless otherwise directed by physician or requested by purchaser.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling dated November 18, 2003.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 8-708/S-023." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call:

Ms. Melissa Robb
Regulatory Project Manager
(301) 594-5313

Sincerely,

{See appended electronic signature page}

Douglas C. Throckmorton, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/

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Doug Throckmorton

12/30/03 11:59:39 AM